

**IRB Study # 07-0190**

**GCRC #: 2579**

**Consent Form Version Date:** 1 June, 2007

**Title of Study:** Cardioprotective Effects of Omega-3 Fatty Acids Supplementation in Healthy Older Subjects Exposed to Diesel Exhaust

*A Pilot Study to Identify the Optimum Diesel Exhaust Concentration to Investigate the Cardiovascular Effects in Healthy Older Subjects*

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**Funding Source:** US Environmental Protection Agency Intramural Federal Research

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**What are some general things you should know about this research study?**

Research studies are designed to gain scientific information that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Research with blood, tissue and/or body fluids (specimens) can help researchers understand how the human body works. Research using specimens can also answer other questions. Many different kinds of studies use specimens. Some researchers may develop new tests to find diseases. Others may develop new ways to treat diseases. In the future, some research may help to develop new products, such as drugs.

You may refuse to allow us to have or store your specimen. If you are a patient with an illness, you do not have to be in the research study in order to receive treatment.

Details are discussed below. It is important that you understand this information so that you can make an informed choice. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

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**What is the purpose of this study?**

Recent reports have shown that people with a particular gene, known as the GSTM1 null gene, are more susceptible to air pollutants such as ozone and diesel exhaust. Another gene called GSTP1 gene is also associated with a significant risk to the effects of air pollutants. The purpose of this pilot study is to look at the cardiovascular and respiratory effects of diesel exhaust in older subjects who do not carry GSTM1 and have different GSTP1 genotypes (Ile/Ile, Ile/Val, and Val/Val). The purpose of this screening session is to determine whether you carry a GSTM1 gene and your GSTP1 genotypes in order for us to make selection.

**How many subjects will participate in this study?**

If you decide to participate, you will be one of approximately 6 participants who will complete in this pilot study.

**How long will your participation last?**

Participation in this genetic screening session of the study will last for approximately 30 minutes.

**What will happen if you participate in this study?**

We will briefly review your medical history and any medical conditions that you have or medications that you are currently taking. You will sign 2 copies of the study consent form. We will measure your blood pressure and draw about 50 ml of blood for genotyping and blood analysis. If you are re-contacted from the previous study, you will not need genotype screening but you will need to get blood drawn for other blood analysis. At the end, we will give you a copy of the Medical History Form and please hold the form until you hear from us that you are qualified for the study, and then fill it out and mail it back to the Westat recruitment office.

**How will the blood sample be collected?**

You will have about 50 ml (about 5 tablespoon) of blood taken by our trained nursing staff.

**What will happen to the blood?**

The blood sample collected will be used to look at the GSTM1 gene and GSTP1 genotypes. If there are excess samples left over after use for the purposes of this specific study, they will be stored at the U.S. Environmental Protection Agency Human Studies Facility located in Chapel Hill North Carolina. Only project members of the study will have access to the samples.

During the course of this research, other researchers may request access to specimens for as-of-yet unspecified research that may or may not be related to the original research from which the specimens were derived. In these cases, provided appropriate IRB approved consent has been obtained from subjects, these specimens will be provided without identifiers to these other researchers by employing a data use agreement.

**Are there any reasons you should not participate?**

You should not participate in this portion of the study if you are not a candidate for the subsequent portions. The inclusion and exclusion criteria will be described. Briefly, you should not have chronic diseases including active allergies, lung diseases, diabetes, need for a heart pacemaker, a previous chest pain and heart attack or coronary bypass surgery and uncontrolled high blood pressure. You are currently taking  $\beta$ -blockers and lipid lowering statins. You need to

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be non-smoker for at least 1 year prior to the study or smoked only little earlier in life. The investigators and medical staff will explain other potential exclusionary conditions in detail to you.

**What are the possible benefits to you?**

There are no direct benefits to you for completing this portion of the study. However, you will know your blood cholesterol levels and you will know your genotype of GSTM1 and GSTP1 genes and this information will determine if you will be qualified for the further diesel exposure study.

**What are the possible risks or discomforts involved with being in this study?**

This study might involve the following minimal risks and/or discomforts to you:

1. The risks associated with taking blood samples are considered minimal. A well-trained member of the staff will draw the blood. Drawing blood could cause some bruising or minor pain, which usually resolves quickly. Also, a rare complication is skin infection or an infection of the vein in which the blood has been drawn. The risk of getting and infection is minimized by the use of sterile technique. If you do have signs of infection at the site (redness, warmth, painful skin, and swelling) after completion of the procedure, you will need to contact the EPA medical station.
2. Risk of breach of confidentiality is minimal. You will be assigned a study number which will be used for data – not your name. The study number is all that will be entered into computer databases. All paper files which may contain your name or screening number are secure in the EPA building which has limited access 24 hours/day. A numeric coding system will be used to ensure that you cannot be directly identified from the samples alone.

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers

**Will there be any cost to you to participate?**

The U.S. EPA will pay the costs of this research. You will not be billed for any procedures.

**Will you receive anything for being in this study?**

You will be paid \$30 for completing this screening procedure. We will give you parking coupons to cover the cost of parking. If you live more than 30 miles outside of the Chapel Hill/Carrboro area, you will be reimbursed for mileage at the current government rate. Money received by participants in research studies is normally treated as ordinary income by taxing authorities and we will report payments made to you to the Internal Revenue Service as required by law.

**Who owns the blood samples?**

Any blood samples obtained for the purpose of this study become the exclusive property of The U.S. Environmental Protection Agency. The researchers may retain, preserve or dispose of these specimens and may use these specimens for research that may result in commercial applications. There are no plans to compensate you for any future commercial use of these specimens.

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**How will your privacy be protected?**

You will be given a study code number. All electronic documents will only have that number. The paper records that the coordinators and medical doctors use may have your name. Your information can be linked to your personal information by the study number, however only study personnel have access to your personal information. Paper records which use your name are kept in a locked file cabinet in the EPA Medical Station of the Human Studies Facility. The Medical Station is locked when not attended by study staff, and the EPA Human Studies Facility has limited access to authorized individuals only, 24 hours/day for 7 days/week. Samples used for genetic analysis will be stored at the EPA Human Studies Facility.

Research studies may be done at many places at the same time. Your personal identifying information will not be sent to outside researchers.

No one will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

**Will researchers seek approval from you to do future studies involving the blood samples?**

By signing this consent form, you are giving your permission for researchers to use your specimens as described above. Current and future research is overseen by a committee called the Institutional Review Board (IRB). The role of the IRB is to protect the rights and welfare of research participants.

In some cases, the IRB may require that you be re-contacted and asked for your consent to use your specimens in a specific research study. You have the right, at that future time, not to participate in any research study for which your consent is sought. Refusal to participate will not affect your medical care or result in loss of benefits to which you are entitled.

**Will you receive study results of future research involving your blood samples?**

Most research with your specimens is not expected to yield new information that would be meaningful to share with you individually. In rare cases, you may be offered the opportunity to receive information about the results of research in which the specimens were used (for example, findings that would affect your medical care).

**Can you withdraw the blood samples from the research study?**

If you decide that you no longer wish for the specimens to be stored, you should contact the researchers on the front page of this form. You may also contact the Institutional Review Board, University of North Carolina at Chapel Hill, 919-966-3113, Medical School Building 52, CB 7097, Chapel Hill, NC 27599, or by email at IRB\_subjects@unc.edu. It is best to make your request in writing.

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Any analysis in progress at the time of your request or already performed prior to your request being received by the researcher will continue to be used as part of the research study. Once the researchers have been notified, your specimens would be destroyed. If you do not make such a request, the specimens may be stored forever. The researchers may choose to destroy the specimens at any time.

**What will happen if you are injured by this research?**

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from having your specimen collected. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. **Neither the University of North Carolina at Chapel Hill nor the U.S. EPA has set aside funds to pay you for any such reactions or injuries, or for the related medical care.** If you believe that you have suffered a research-related injury, you have the right to pursue legal remedy if you believe that your injury justifies such action. The Federal Tort Claims Act, 28 U.S.C. S 2671 et seq., provides for money damages against the United States when property loss or personal injury results from negligent or wrongful act or omission of any employee of the EPA while acting within the scope of his or her employment. Signing this consent form does not waive any of your legal rights or release the investigator, the sponsor, the institution, or its agents from liability for negligence. If a research-related injury occurs, you should contact the Director of the EPA NHEERL Human Research Protocol Office at 919-966-6217.

**Who is sponsoring this study?**

This research is funded by The U.S. Environmental Protection Agency. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

**What if you have questions about this study?**

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, you should contact the researchers listed on the first page of this form or the EPA Director of the National Health and Environmental Effects Human Research Laboratory Protocol Office at 919-966-6217.

**What if you have questions about your rights as a research subject?**

All research on human subjects is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously, if you wish, the Institutional Review Board at 919-966-3113 or by email to [IRB\\_subjects@unc.edu](mailto:IRB_subjects@unc.edu) and/or the EPA Director of the National Health and Environmental Effects Human Research Laboratory Protocol Office at 919-966-6217.

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**Subject's Agreement:**

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate. I agree to my specimen(s) being stored with the identifying code(s).

\_\_\_\_\_  
Signature of Research Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Research Subject

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Person Obtaining Consent